

## **NC Hospital Association Best Practices Principles**

**From: Hugh Tilson, Senior Vice President, NC Hospital Association**

**December 4, 2012 – FINAL DRAFT**

### **PRINCIPLES:**

Hospitals and labs in North Carolina will ensure that the procedures to request patients' pathological materials comply with the following general principles.

Hospitals and labs that cannot comply with the following principles for any request, in order to ensure that patient specimens are retained for compliance with federal law, accreditation standards, evidentiary standards, or in order to protect medically necessary specimens for the patient's further diagnosis and treatment, shall provide the reason(s) for not complying to the requestor.

#### **A. MATERIALS FOR ONGOING PATIENT CARE**

To meet ongoing patient care and accreditation/regulatory compliance requirements, original slides and blocks remain in [LAB/SYSTEM NAME] files as part of the patient's permanent medical record.

A copy of [LAB/SYSTEM NAME] report will be sent to the patient or another medical institution caring for the patient upon request.

Recut sections and unstained slides when requested will be sent to other medical institutions or physicians for continued patient care or for consultation upon request unless inadequate supply of sample exists or if recutting would damage the sample. The original sample or block shall not be forwarded, unless deemed appropriate by the [LAB/SYSTEM NAME].

#### **B. RESEARCH REQUESTS:**

For researchers not within [LAB/SYSTEM NAME], the researchers must document IRB approval at their institution. Once that is received, a [LAB/SYSTEM NAME] pathologist will ascertain what materials are present in [LAB/SYSTEM NAME] files and which may be recut for research purposes. No blocks will be forwarded from [LAB/SYSTEM NAME] for research purposes, unless deemed appropriate by [LAB/SYSTEM NAME]. If sufficient tissue is present, the outside researcher will be offered recut or unstained sections.

For researchers within [LAB/SYSTEM NAME], the request must be reviewed by a designated pathologist or the pathologist who signed the case out who will determine whether sufficient tissue is present to recut the blocks.

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### C. REQUESTS FROM LAW FIRMS AND DOCUMENT RETRIEVAL FIRMS:

An appropriate authorization for release of medical records and unstained or new prepared hematoxylin and eosin (H&E) stained slides must accompany the request and must meet the following criteria (including, but not limited to)

- Signed within the last year
- Signed by the patient, a legal guardian or the executor of the patient's estate

In addition, a written signed request must be submitted by a law firm, together with information about reimbursement of cost for the slides. Unless the [LAB/SYSTEM NAME] has an objection on other grounds (including compliance with federal law, accreditation standards, evidentiary standards, or in order to protect medically necessary specimens for the patient's further diagnosis and treatment), no court order should be required for new slides.

In any case, the laboratories should make available to the attorney's expert witness a place in the laboratory where the original slides (and blocks if that matters) can be examined at a mutually agreeable time, which obviates harm to the integrity of the patient's medical record or specimen retention requirements. Digital scanning of slides at levels equivalent to the original slides themselves is a technology becoming available, which also obviates any damage to the tissues. The foregoing authorizations are required in these cases as well.

### D. ACCREDITATION/REGULATORY COMPLIANCE

Recut sections will be provided when available.

To ensure compliance with federal law, accreditation standards, evidentiary standards, or in order to protect medically necessary specimens for the patient's further diagnosis and treatment, original slides and/or paraffin blocks will be provided only upon receipt of a Court Order or subpoena from a court with appropriate jurisdiction.

Reasonable fees may be charged for the provision of documents, recut sections or other materials provided.